

# EXHIBIT 3

Version of September 27, 1984

## HYDROCARBON CONTAMINATION OF GROUNDWATER

### TOXICOLOGY OVERVIEW

#### BACKGROUND

Groundwater is recognized as an invaluable natural resource, used by society for human consumption, crop irrigation, for watering livestock, as a source for industrial water, and geothermal energy. Contamination of groundwater by hydrocarbons due to the accidental spillage/leakage of gasoline into the environment is therefore of high concern to the Petroleum Industry. Several of the American Petroleum Institute's technical committees are now addressing various aspects of the groundwater issue.

For purposes of this discussion, it may be helpful first to consider the complexities of an hypothetical gasoline spill/leak in order to appreciate fully the variety of factors involved. When a complex petroleum hydrocarbon mixture like gasoline is spilled/leaked onto the ground, the liquid is quickly absorbed into the soil by capillary action. Several processes may then come into play-- volatilization of lighter components from the surface of the spill site, biological degradation, adsorption of certain components onto soil particles and humus, soil-catalyzed chemical degradation, autooxidation, photolysis, etc. It is important to note that as a result of these processes, the hydrocarbon mixture of environmental concern may differ substantially from the original gasoline liquid spilled.

With regard to groundwater, hydrocarbon contaminants may exist in two forms. If the spill/leak is of such a magnitude that the gasoline directly contacts the water table, small micelles of gasoline may be present in suspension in the groundwater. However, in general micelles are of relatively low human health concern since they are found only if a water well is in close proximity to the spill site, and because gasoline micelles would adversely affect both the odor and taste properties of the water. Soluble compounds (components of gasoline and/or degradation products) are considered to be of greater concern from the human health point-of-view. Such materials would enter the groundwater by direct extraction (if the spilled gasoline

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directly contacts the water table) or from rain water as it percolates through the contaminated soil.

Groundwater occurs in the porous spaces between particles of soil and rock, not as large underground rivers and streams as is commonly misconceived. Groundwater moves relatively slowly with estimates ranging from 5 feet per day to as little as five feet per year. As the water moves through the soil, the soluble compounds are selectively adsorbed/desorbed on the soil particles resulting in the chromatographic separation of the specific soluble compounds. It is common therefore to identify multiple plumes of gasoline-associated compounds being carried by the groundwater from the site of an accidental spill/leak incident. Oxygenates such as methyl tertiary-butyl ether (MTBE) and various alcohols often migrate together as a relatively early plume; soluble aromatic compounds such as benzene and toluene often migrate together as a somewhat later plume. It should be appreciated therefore that the specific gasoline-associated contaminants contained in water derived from a particular well can vary significantly over time, as one plume migrates beyond the water well and is replaced by a second, chemically distinct plume of material. Several years may be required for major contaminant plumes to migrate beyond a particular well site.

The contamination of groundwater by gasoline-associated compounds raises numerous questions of relevance:

1. Is the water "safe" to drink?...to bathe in?...to wash fruit and vegetables?...to cook with?...to water pets and livestock?...to irrigate crops?...to water the lawn?
2. Will the organoleptic (odor and taste) properties of the contaminants provide an adequate warning that contamination of groundwater has occurred?
3. Are the organoleptic properties of contaminated water such that people would refuse to drink it?

As noted above, many of these questions are being addressed by various API technical committees. The need for intra-API coordination is appreciated.

#### ISSUES TO BE RESOLVED

A basic question considered by the Task Force was "Can the API Toxicology Committee develop data which would be useful for determining the safety of groundwater?" The Task Force believes that animal toxicology data can make a contribution

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to the issue. It remains to be determined, however, the extent to which such data will have to be developed by additional animal studies.

It should be appreciated that the development of protocols for specific toxicological studies may be the easiest aspect of any research program dealing with the contamination of groundwater by gasoline spills/leaks; several major issues must be resolved by the API prior to the initiation of animal experiments. Resolution of these issues is considered to be beyond the authority of this Task Force.

#### Issue 1. Purpose of Proposed Toxicological Studies:

In discussions of the complexity of the groundwater issue, a number of highly diverse viewpoints have been expressed concerning the purpose of the proposed toxicological research program. The Task Force is seeking guidance from appropriate groups within the API as to which perceived purpose should indeed be given highest priority by the API Toxicology Committee. As discussed below, concurrence within the Industry with regard to the specific purpose of the API research program is necessary for determining the nature of the test material to be used in animal studies.

- a. To Assess the Toxic Potential of Water Saturated with Gasoline Hydrocarbons: It has been argued that the Toxicology Committee should assess the toxic potential of drinking water contaminated to an extreme degree. Thus, if no adverse effects are noted in such extreme studies, some assurance can be given to community leaders and others concerned with the health aspects of groundwater contamination. Several suggestions have been made as to how best to define the water sample to be used in animal studies. One possibility is to use an aqueous extract of gasoline, which would in fact likely contain a greater number of gasoline components than would an actual groundwater sample. A second suggestion is to use a synthetic mixture of major gasoline-associated compounds in drinking water, each at its odor and/or taste threshold concentration. Alternatively, this synthetic hydrocarbon mixture could be blended such that each component is present at its solubility limit in water.
- b. To Assess the Toxic Potential of "Real World" Water Contamination: According to this view, the Toxicology Committee's research efforts should focus on those gasoline-associated contaminants identified in "real world"

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gasoline leak/spill incidents, at concentrations approximating those in "real world" situations. The test material in this case might be a synthetic mixture of gasoline-associated compounds in drinking water based on data from the API Ad Hoc Committee on Groundwater.

c. To Provide Data on Individual Gasoline Components: According to this view, the attention of regulatory authorities and others may focus on specific components of gasoline (e.g., benzene, EDB, MTBE, etc.) and water quality criteria will be established for each individually. Thus, it could be argued that the Toxicology Committee most appropriately should conduct drinking water studies on each of the major gasoline components of concern. Such studies would develop data which would be useful in developing appropriate water quality criteria for each identified component. Such studies might also develop data appropriate for quantitative risk modeling purposes.

d. To Provide Data on Benzene: It has been suggested that of the various soluble components of gasoline, benzene is the compound of greatest health concern and is therefore what various authorities will use as their primary criterion of potability. Thus, according to this view, the Toxicology Committee's test material should consist only of benzene in drinking water.

Issue 2: Oxygenates and Other Additives: It has been suggested that oxygenates such as methyl tertiary-butyl ether (MTBE) are proprietary chemical additives to gasoline and therefore should not be included in the API test program. Similar arguments have been stated for lead compounds and scavengers such as ethylene dibromide (EDB). However, MTBE and other oxygenates, because of their odor and taste properties and because of their high solubility in water, are often the first indicators that a gasoline spill/leak has occurred and has contaminated the groundwater. Thus, it seems likely that from the practical point-of-view it may be impossible to divorce the groundwater contamination issue from oxygenates. It would seem prudent for API to deal with all aspects of the problem in its test program. In the case of EDB, the cancer concerns associated with this compound also suggest that it may be prudent for API to include leaded gasolines in its considerations.

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## TOXICOLOGY STUDIES UNDER CONSIDERATION

The Task Force has considered in detail various health issues associated with the contamination of groundwater by gasoline spills/leaks. As a result of these discussions the following biological endpoints were identified and prioritized for their probable relevance to the interests of the API: Hematotoxicity > Carcinogenicity > Reproductive Toxicity and Teratogenicity > Genotoxicity > Neurotoxicity and/or Nephrotoxicity. To assess such toxic effects various activities and studies are being considered:

1. Review of Available Toxicological Information: A review of relevant toxicological information on major gasoline components commonly identified in contaminated groundwater was proposed and accepted by the Task Force. This survey will provide a basis for determining whether the biological endpoints identified by the Task Force need to be addressed in further animal studies. Likewise, because many of the animal studies discussed below would require several years to complete, this review will provide an interim toxicology data package for field use in answering health questions from community leaders and others. The gasoline components tentatively identified by the Task Force for this review are benzene; toluene; m- and p-xylene; ethylbenzene; 1,2,4-trimethylbenzene; 2,2,4-trimethylbenzene; m- and p-ethyltoluene; naphthalene; indane; methanol; t-butyl alcohol; methyl t-butyl ether (MTBE); ethylene dibromide (EDB); ethylene dichloride (EDC); and 1,2-dichloroethane.
2. Subacute Pilot Study: It is anticipated that any animal test program utilizing drinking water containing gasoline-associated compounds will require certain preliminary data to be developed. Among the questions to be addressed is "how often must the drinking water sample be reformulated/changed to assure that the concentration of the volatile gasoline-associated compounds are within acceptable limits?" Likewise, "are the organoleptic properties of the drinking water sample such that the animals will refuse to drink it?"
3. Hydrocarbon Bioavailability: Quantitative estimation of the extent to which selected gasoline-associated compounds are absorbed from drinking water and are distributed among the major body tissues is being considered by the Task Force.
4. Genetic Toxicity Studies: Selected in vivo and in vitro assays are being considered by the

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Task Force. Micronuclei in the bone marrow, marrow cytogenetics, sperm morphology, sperm cytogenetics may be evaluated as part of subacute animal studies. A separate evaluation of the ability of the selected test material to induce unscheduled DNA synthesis in rodent liver and/or kidney is under consideration, and would be coordinated with a similar program on unleaded gasoline currently in progress at CIIT. *Salmonella* mutagenesis assays, a mammalian cell gene mutation assay, and cytogenetics in cultured CHO cells are being considered to examine the potential of gasoline-associated components to cause genetic damage in vitro. Such tests would likely utilize concentrates of the water-soluble components (prepared with XAD resins as per EPA and New Jersey DEP procedures), and would be conducted contingent on results of long-term studies, regulatory developments, or by direction from management.

5. 90-Day Drinking Water Studies in Two Species:  
These studies will provide a basis for selecting appropriate dose levels for longer term toxicity studies.
6. Chronic Drinking Water Studies in Two Species:  
These studies will assess the potential of prolonged exposure to contaminated water to produce toxic effects and/or cancer.
7. Two-Generation Reproduction/Teratology: A drinking water study in Sprague-Dawley rats is being considered to assess the toxic potential of contaminated water to affect reproductive function and/or the embryo/fetus.

Basic study designs for the above are appended. It should be appreciated that these experimental designs are intended primarily to identify the hazards associated with the contamination of drinking water by gasoline-associated compounds and would provide only limited data for quantitative risk modeling exercises. This approach is considered by the Task Force to be the most cost-efficient of the research alternatives presently available. Should API management later decide that risk data are worthwhile, experiments can then be designed to assess the specific hazards identified in the above research program.

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## API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK FORCE

### SUBACUTE PILOT STUDY

PURPOSE: To develop necessary expertise in performing toxicological studies utilizing drinking water contaminated with volatile gasoline-associated compounds.

#### SALIENT ASPECTS OF STUDY DESIGN:

- 2 suitable test species
- Exposure duration--2 weeks
- Test material--drinking water; composition to be determined
- Control and 3 "Treatment" Groups
- Doses--to be determined
- Animal Observations--daily water consumption, weekly body weights, full necropsy and histopathological exam, selected clinical chemistry and hematologic examination, selected immunological function tests
- Chemical analyses (as appropriate) of the concentrations of major gasoline-associated compounds in the drinking water to assess stability of the test material.
- Statistical evaluation of results

ANTICIPATED DURATION: 6 months

ESTIMATED COST: \$35,000

CONSIDERATIONS: This study will provide data considered necessary for the design and conduct of subsequent toxicological investigations of the toxic potential of drinking water contaminated by a gasoline spill/leak. Depending on the nature of the test material and the doses selected by API, it is possible that adverse health effects could be identified in the present study. Such findings would need to be addressed by appropriate experts and by API member companies for their relevance to human health, as well as to the overall scope of this research program.

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API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK  
FORCE

HYDROCARBON BIOAVAILABILITY

PURPOSE: To characterize the extent to which major gasoline-associated compounds are absorbed from drinking water. Some attempt to determine the relative tissue distribution of these compounds may also be made.

SALIENT ASPECTS OF STUDY DESIGN:

- 2 suitable species
- Selected gasoline-associated compounds to be administered by gavage.
- Doses to be determined.
- Methods will be developed to quantitate that portion of the administered dose appearing in the blood and/or urine; other tissues.

ANTICIPATED DURATION: 8 months

ESTIMATED COST: \$25,000

CONSIDERATIONS: It is anticipated that the data developed by this study will be useful in assessing the relevance of data from drinking water studies using experimental animals to human health. Such data may also be useful in quantitative risk modelling exercises for selecting appropriate dose estimates, should such modelling techniques become required in the future.

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API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK  
FORCE

IN VIVO GENETIC TOXICOLOGY STUDIES -

PURPOSE: To assess the mutagenic potential in intact animals of gasoline-associated compounds in drinking water.

SALIENT ASPECTS OF STUDY DESIGN:

- Tests under consideration include
  - a. In vivo bone marrow cytogenetics assay
  - b. In vivo bone marrow micronucleus assay
  - c. Sperm morphology assay
  - d. Sperm cytogenetics assay
  - e. Unscheduled DNA synthesis in liver, and possibly kidney--this program to be coordinated with similar studies at CIIT on unleaded gasoline.
- These endpoints will be included as part of the subacute pilot study and/or the 90-day drinking water study.

ANTICIPATED DURATION: See subacute and 90-day study designs.

ESTIMATED COST: \$20,000 for tests a-d  
\$20,000 for test e

CONSIDERATIONS: The studies under consideration would provide data to assess the genotoxic potential of gasoline-associated compounds in drinking water. Such data might be extremely useful for defining appropriate health guidance if, for example, tumors are observed in the chronic bioassay since it might be possible to distinguish between a direct and an indirect carcinogenic effect.

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API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK  
FORCE

IN VITRO GENETIC TOXICITY STUDIES

PURPOSE: To assess the genotoxic potential of concentrated preparations of gasoline-associated compounds in groundwater using in vitro screening assays. Such assays are presently under consideration by several regulatory authorities for environmental monitoring purposes.

SALIENT ASPECTS OF STUDY DESIGN:

- Water-soluble compounds in the drinking water test samples being used in the API toxicology program, or in environmental samples of contaminated groundwater, will be concentrated over XAD resins according to EPA or New Jersey DEP procedures.
- Concentrates of the water-soluble fraction would be tested in the following assays:
  - a. Ames Salmonella assay
  - b. Mammalian gene mutation assay
  - c. In vitro cytogenetics assay in CHO cells

ANTICIPATED DURATION: 6 months

ESTIMATED COST: \$11,000

CONSIDERATIONS: The Task Force is concerned by the high likelihood of "irrelevant" mutagenic activity to be identified in these extremely concentrated preparations of gasoline-associated compounds, and therefore is only considering these studies contingent on the results of long-term studies, regulatory developments, or on the explicit direction of API management. It should be recognized, however, that some familiarity of the strength and weaknesses of the methods described here should be developed within the API in order to assure the industry's ability to respond appropriately to possible regulatory requirements.

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API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK  
FORCE

90-DAY DRINKING WATER STUDY

PURPOSE: To provide information concerning the toxic potential resulting from the subchronic administration of drinking water containing gasoline-associated compounds.

SALIENT ASPECTS OF STUDY DESIGN:

- 2 suitable test species
- Exposure duration--90 days
- Test material--drinking water; composition to be determined
- Control and 3 "Treatment" Groups
- Dosages--to be determined
- Sacrifices--45 and 90 days
- Animal Observations--daily water consumption, weekly body weights, full necropsy and histopathological exam, selected clinical chemistry and hematologic examination
- Chemical analyses (as appropriate) of the concentrations of major gasoline-associated compounds in the drinking water.
- Statistical evaluation of results
- Selected genotoxicity endpoints may be included (see separate study outline)

ANTICIPATED DURATION: 18 months

ESTIMATED COST: \$250,000

CONSIDERATIONS: The primary purpose of this study is to provide data suitable for selecting appropriate exposure levels for a subsequent chronic toxicity/carcinogenesis bioassay.

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API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK  
FORCE

CHRONIC DRINKING WATER STUDY

PURPOSE: To provide information concerning the toxic potential resulting from the chronic administration of drinking water containing gasoline-associated compounds.

SALIENT ASPECTS OF STUDY DESIGN:

- 2 suitable test species
- Exposure duration--lifetime, or appropriate period
- Test material--drinking water; composition to be determined
- Control and 3 "Treatment" Groups
- Dosages--to be determined based on results from 90-day study
- Sacrifices--3, 6, 12, 18 months, and termination
- Animal Observations--periodic water consumption, weekly body weights, full necropsy and histopathological exam, selected clinical chemistry and hematologic examination
- Chemical analyses (as appropriate) of the concentrations of major gasoline-associated compounds in the drinking water.
- Statistical evaluation of results

ANTICIPATED DURATION: 3 years

ESTIMATED COST: \$3,000,000

CONSIDERATIONS: This study will examine the potential for chronic toxicity and carcinogenicity resulting from the long-term ingestion of gasoline-associated compounds via the drinking water.

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## API TOXICOLOGY OF GASOLINE IN GROUNDWATER TASK FORCE

### 2-GENERATION REPRODUCTION/TERATOLOGY STUDY

**PURPOSE:** To assess the teratogenic potential and effects on reproductive capacity and performance of gasoline-associated compounds administered in the drinking water of rats.

#### SALIENT ASPECTS OF STUDY DESIGN:

- Test species--Sprague-Dawley rat
- F0 male and female rats will be exposed for 80 days prior to the three-week mating period
- Test material--drinking water; composition to be determined
- Control and 3 "Treatment" Groups
- Dosages--to be determined
- Selected F0 dams from each dose level and the control group will be sacrificed on the 20th day of gestation for teratological evaluation.
- Remaining F0 dams are allowed to deliver (F1 pups), and the F0 mating is evaluated for any apparent treatment-related adverse effects; if adverse effects noted the F0 males and females will be continued on treatment to produce a second litter.
- Selected males and females from the F1 generation will be mated to produce the F2 generation; survival of the F2 pups will be evaluated.
- Chemical analyses (as appropriate) of the concentrations of major gasoline-associated compounds in the drinking water.
- Statistical evaluation of results.

**ANTICIPATED DURATION:** 12 months

**ESTIMATED COST:** \$250,000

**CONSIDERATIONS:** A two-generation study is being considered because drinking water exposures can potentially occur throughout an individual's life, beginning in utero or during childhood. A full teratology study is being considered (rather than with dams from only the highest dose level and the control group) because teratology data on hydrocarbon mixtures administered in drinking water are unavailable. Using parents which are exposed prior to and during mating and gestation is felt to match most closely potential human exposure patterns.

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